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IDS Form PTO/SB/08: Substitute for form 1449A/PTO

Complete if Known

**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**

(Use as many sheets as necessary)

Sheet

1

of

3

Application Number

10/600,004

Filing Date

June 18, 2003

First Named Inventor

Kelly

Art Unit

1614

Examiner Name

Delacroix-Muirheid, Cybille

Attorney Docket Number

07579.0015-01000

U.S. PATENTS AND PUBLISHED U.S. PATENT APPLICATIONS

| Examiner Initials* | Cite No. | Document Number | Issue or Publication Date MM-DD-YYYY | Name of Patentee or Applicant of Cited Document | Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear |
|-----------------------|-------------|-----------------------------|--|--|---|
| | | Number-Kind Code (if known) | | | |
| CDM | | US 2005/0036962 A1 | 02-17-2005 | Kelly et al. | |
| | | US 2005/0049424 A1 | 03-03-2005 | Kelly et al. | |
| | | US 2005/0059616 A1 | 03-17-2005 | Kelly et al. | |
| | | US 2005/0143588 A1 | 06-30-2005 | Heaton et al. | |
| | | US 5,637,598 | 06-10-1997 | Grese | |
| | | US 6,033,714 | 03-07-2000 | Gugger et al. | |
| | | US 6,987,098 B2 | 01-17-2006 | Kelly | |

FOREIGN PATENT DOCUMENTS

| Examiner Initials* | Cite No. | Foreign Patent Document | Publication Date MM-DD-YYYY | Name of Patentee or Applicant of Cited Document | Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear | Translation |
|-----------------------|-------------|--|--------------------------------|--|---|-------------|
| | | Country Code Number Kind Code (if known) | | | | |
| CDM | | EP 0 682 877 B1 | 04-02-2003 | Nichimo Co. Ltd. | | |
| | | WO 98/21946 A1 | 05-28-1998 | Internutria, Inc. | | |
| | | WO 98/25460 A1 | 06-18-1998 | Zymogenetics, Inc. | | |
| | | WO 99/45923 A1 | 09-16-1999 | Merck & Co., Inc. | | |
| | | WO 00/16759 A2 | 03-30-2000 | Schnyder | | |
| | | WO 00/54753 A2 | 09-21-2000 | Johnson & Johnson Consumer Companies, Inc. | | |

NON PATENT LITERATURE DOCUMENTS

| Examiner Initials* | Cite No. | Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published. | Translation |
|-----------------------|-------------|--|-------------|
| CDM | | "Novogen launches Rimostil," Press Release, 2 pages, http://www.novogen.com/news/newsPopup.cfm?id=22 (June 22, 2000). | |
| | | BABER, R. et al. "The effect of an isoflavone dietary supplement (Rimostil™) on serum lipids, forearm bone density and endometrial thickness in post-menopausal women," <i>10th Annual Meeting of the North American Menopause Society</i> , New York, 4 pages (September 1999). | |
| | | CASWELL, A. (Ed.) "Hypolipidaemic agents," <i>MIMS Annual</i> , 23 rd Edition, pp. 2-152 to 2-168, Tien Wah Press, Singapore (1999). | |
| | | CHANG, Y-C. et al., "Microwave-mediated synthesis of anticarcinogenic isoflavones from soybeans," <i>J Agric Food Chem.</i> 42:1869-1871 (1994). | |

| | | | | | |
|---|---|----|---|--------------------------|-----------------------------|
| IDS Form PTO/SB/08: Substitute for form 1449A/PTO | | | | Complete if Known | |
| INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Use as many sheets as necessary) | | | | Application Number | 10/600,004 |
| | | | | Filing Date | June 18, 2003 |
| | | | | First Named Inventor | Kelly |
| | | | | Art Unit | 1614 |
| | | | | Examiner Name | Delacroix-Muirheid, Cybille |
| Sheet | 2 | of | 3 | Attorney Docket Number | 07579.0015-01000 |

| NON PATENT LITERATURE DOCUMENTS | | | | | |
|---------------------------------|--|--|--|--|-------------|
| CDM | | | CLIFTON-BLIGH, P. et al., "The effect of isoflavones extracted from red clover (Rimostil™) on lipid and bone metabolism," <i>Menopause</i> 8(4):259-265 (2001). | | |
| | | | DIXON, R. et al., "Molecular controls for isoflavonoid biosynthesis in relation to plant and human health," <i>Phytochemicals in Human Health Protection, Nutrition and Plant Defense</i> , Kluwer Academic, New York, pp. 133-159 (1999). | | |
| | | | DÖREN, M. et al., "Identification and treatment of postmenopausal women at risk for the development of osteoporosis," <i>Intl. J. Clin. Pharmacology, Therapy and Toxicology</i> 30(11):431-433 (1992). | | |
| | | | GOH, J.T.W. et al., "Postmenopausal endometrioma and hormonal replacement therapy," <i>Aust NZ J. Obstet. Gynaecol.</i> 32(4):384-385 (1992). | | |
| | | | GOLDMAN, L. et al., "Cost and health implications of cholesterol lowering," <i>Circulation</i> 85(5):1960-1968 (1992). | | |
| | | | GRAHAM, T.L., "Flavonoid and isoflavonoid distribution in developing soybean seedling tissues and in seed and root exudates," <i>Plant Physiol.</i> 95:594-603 (1991). | | |
| | | | GRODSTEIN, F. et al., "Postmenopausal hormone use and cholecystectomy in a large prospective study," <i>Obstet. Gynecol.</i> 83(1):5-11 (1994). | | |
| | | | HULLEY, S. et al., "Randomized trial of estrogen plus progestin for secondary prevention of coronary heart disease in postmenopausal women," <i>JAMA</i> 280(7):605-613 (1998). | | |
| | | | KELLY, S.A. et al., "Protein tyrosine phosphorylation mediates TNF-induced endothelial-neutrophil adhesion in vitro," <i>Am. J. Physiol. (274 Heart Circ. Physiol. 43):H513-H519</i> (1998). | | |
| | | | KNIGHT, D. et al., "Phytoestrogens - a short review," <i>Maturitas</i> 22(3):167-175 (1995). | | |
| | | | MAY, M.J. et al., "Effects of protein tyrosine kinase inhibitors on cytokine-induced adhesion molecule expression by human umbilical vein endothelial cells," <i>Br. J. Pharmacol.</i> 118(7):1761-1771 (1996). | | |
| | | | Oenobiol Feminite Dietary Supplement, International Product Alert Vol. 16, No. 12, and product inserts, 3 pages (1999). | | Translation |
| | | | PALMETSHOFER, A. et al., "α-Galactosyl epitope-mediated activation of porcine aortic endothelial cells," <i>Transplantation</i> 65(7):971-978 (1998). | | |
| | | | PARFITT, K. (Ed.), <i>Martindale, The complete drug reference</i> , 32nd Edition, Pharmaceutical Press, London, Table of Contents, pp. v and vi (1999). | | |
| | | | PEDERSON, T. et al., "Randomised trial of cholesterol lowering in 4444 patients with coronary heart disease: the Scandinavian Simvastatin Survival Study (4S)," <i>The Lancet</i> 344:1383-1389 (1994). | | |
| | | | SACKS, F. et al., "The effect of pravastatin on coronary events after myocardial infarction in patients with average cholesterol levels," <i>The New England Journal of Medicine</i> 335(14):1001-1009 (1996). | | |
| | | | SBAROUNI, E. et al., "The effect of hormone replacement therapy alone and in combination with simvastatin on plasma lipids of hypercholesterolemic postmenopausal women with coronary artery disease," <i>J. Am. Coll. Cardiol.</i> 32(5): 1244-1250 (1998). | | |
| | | | STAMPFER, M. et al., "A prospective study of cholesterol, apolipoproteins, and the risk of myocardial infarction," <i>The New England Journal of Medicine</i> 325(6):373-381 (1991). | | |
| | | | TAMURA, S. et al., "Chemical studies on 'Clover Sickness' Part I. Isolation and structural elucidation of two new isoflavonoids in red clover," <i>Agr. Biol. Chem.</i> 33(3):391-397 (1969). | | |
| | | | WANG, H.J. et al., "Isoflavone content in commercial soybean foods," <i>J. Agric. Food Chem.</i> 8:1666-1673 (1994). | | |
| ✓ | | | WEIDENBÖRNER, M., et al., "Antifungal activity of isoflavonoids in different reduced stages on <i>Rhizoctonia solani</i> and <i>Sclerotium rolfsii</i> ," <i>Phytochemistry</i> 29(3):801-803 (1990). | | |

| | | | | | |
|---|---|----|---|--------------------------|-----------------------------|
| IDS Form PTO/SB/08: Substitute for form 1449A/PTO | | | | Complete if Known | |
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| NON PATENT LITERATURE DOCUMENTS | | |
|---------------------------------|---|--|
| | Office Action issued in U.S. Patent No. 6,340,703 on July 9, 1999 (Attorney Docket No. 07579.0006-00000). | |
| | Office Action issued in U.S. Patent No. 6,340,703 on April 27, 2000 (Attorney Docket No. 07579.0006-00000). | |
| | Amendment and Response filed in U.S. Patent No. 6,340,703 on October 27, 2000 (Attorney Docket No. 07579.0006-00000). | |
| | Office Action issued in U.S. Patent No. 6,340,703 on February 9, 2001 (Attorney Docket No. 07579.0006-00000). | |
| | Amendment filed in U.S. Patent No. 6,340,703 on May 31, 2001 (Attorney Docket No. 07579.0006-00000). | |
| | Office Action issued in U.S. Patent Application No. 09/986,509 on July 23, 2002 (Attorney Docket No. 07579.0006-01000). | |
| | Amendment filed in U.S. Patent Application No. 09/986,509 on December 23, 2002 (Attorney Docket No. 07579.0006-01000). | |
| | Office Action issued in U.S. Patent Application No. 09/986,509 on February 6, 2004 (Attorney Docket No. 07579.0006-01000). | |
| | Amendment and Response filed in U.S. Patent Application No. 09/986,509 on August 5, 2004 (Attorney Docket No. 07579.0006-01000). | |
| | Office Action issued in U.S. Patent Application No. 09/986,509 on October 24, 2005 (Attorney Docket No. 07579.0006-01000). | |
| | Amendment and Response to Office Action filed in U.S. Patent Application No. 09/986,509 on April 24, 2006 (Attorney Docket No. 07579.0006-01000). | |
| | Office Action issued in U.S. Patent No. 6,599,536 on October 23, 2001 (Attorney Docket No. 07579.0013-00000). | |
| | Amendment filed in U.S. Patent No. 6,599,536 on March 25, 2002 (Attorney Docket No. 07579.0013-00000). | |
| | Office Action issued in U.S. Patent No. 6,599,536 on June 18, 2002 (Attorney Docket No. 07579.0013-00000). | |
| | Amendment and Response After Final filed in U.S. Patent No. 6,599,536 on December 17, 2002 (Attorney Docket No. 07579.0013-00000). | |
| | Notice of Allowance with Statement of Reasons issued in U.S. Patent No. 6,599,536 on April 8, 2003 (Attorney Docket No. 07579.0013-00000). | |
| | Preliminary Amendment filed in U.S. Patent Application No. 10/459,537 on June 12, 2003 (Attorney Docket No. 07579.0013-01000). | |
| | Office Action mailed in U.S. Patent Application No. 10/459,537 on December 20, 2005 (Attorney Docket No. 07579.0013-01000). | |
| | Office Action mailed in U.S. Patent Application No. 09/914,035 on December 18, 2002 (Attorney Docket No. 07579.0015-00000). | |

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|--------------------|---------------------------|-----------------|---------|
| Examiner Signature | <i>Cybele Delacroix-M</i> | Date Considered | 6-26-06 |
|--------------------|---------------------------|-----------------|---------|

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